

| | | |
|---|--|--|
| TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371 | | ATTORNEY DOCKET NUMBER 01-769 |
| INTERNATIONAL APPLICATION NO PCT/FR00/01872 | INTERNATIONAL FILING DATE June 30, 2000 | U.S. APPLICATION NO. (If known see 37 CFR 1.5) 10/019715 |
| TITLE OF INVENTION FIXING ELEMENT AND ANCILLARY FOR STABILISING VERTEBRAE | | |
| APPLICANT(S) FOR DO/EO/US GERARD VANACKER ET AL. | | |
| Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information | | |
| 1. <input checked="" type="checkbox"/> This is a FIRST submission of items concerning a filing under 35 U.S.C. 371 2. <input type="checkbox"/> This is a SECOND or SUBSEQUENT submission of items concerning a filing under 35 U.S.C. 371 3. <input type="checkbox"/> This is an express request to begin national examination procedures (35 U.S.C. 371(f)). The submission must include items (5), (6), (9) and (21) indicated below. 4. <input checked="" type="checkbox"/> The US has been elected by the expiration of 19 months from the priority date (Article 31) 5. <input checked="" type="checkbox"/> A copy of the International Application as filed (35 U.S.C. 371(c)(2)) a. <input checked="" type="checkbox"/> is attached hereto (required only if not communicated by the International Bureau) b. <input type="checkbox"/> has been communicated by the International Bureau. c. <input type="checkbox"/> is not required, as the application was filed in the United States Receiving Office (RO/US). 6. <input type="checkbox"/> An English language translation of the International Application as filed (35 U.S.C. 371(c)(2)). a. <input type="checkbox"/> is attached hereto. b. <input type="checkbox"/> has been previously submitted under 35 U.S.C. 154(d)(4). 7. <input type="checkbox"/> Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3)) a. <input type="checkbox"/> are attached hereto (required only if not communicated by the International Bureau). b. <input type="checkbox"/> have been communicated by the International Bureau. c. <input type="checkbox"/> have not been made; however, the time limit for making such amendments has NOT expired. d. <input type="checkbox"/> have not been made and will not be made 8. <input type="checkbox"/> An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)) 9. <input checked="" type="checkbox"/> An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)). (Informal) 10. <input type="checkbox"/> An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)). | | |
| Items 11 to 20 below concern document(s) or information included: | | |
| 11. <input type="checkbox"/> An Information Disclosure Statement under 37 CFR 1.97 and 1.98. 12. <input type="checkbox"/> An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included. 13. <input type="checkbox"/> A FIRST preliminary amendment. 14. <input type="checkbox"/> A SECOND or SUBSEQUENT preliminary amendment. 15. <input type="checkbox"/> A substitute specification. 16. <input type="checkbox"/> A change of power of attorney and/or address letter. 17. <input type="checkbox"/> A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 35 U.S.C. 1.821 - 1.825. 18. <input type="checkbox"/> A second copy of the published international application under 35 U.S.C. 154(d)(4) 19. <input type="checkbox"/> A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4). 20. <input checked="" type="checkbox"/> Other items or information: Form PCT/IB/306 Form PCT/IB/308 Form PCT/IPEA/409 | | |
| I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail in an envelope addressed to: U.S. Patent and Trademark Office, P.O. Box 2327, Arlington, VA 22202 on December 28, 2001. | | |

page 1 of 2

 EXPRESS MAIL NO.:
 EL398538744US

 Nicole Motzer
 Nicole Motzer

 December 28, 2001
 Date of Signature

01-765

FORM PTO-1390 (REV 9-2001) page 2 of 2

THE **WORLD'S** **LARGEST** **BOOKSTORE**

FIXING ELEMENT AND ANCILLARY FOR STABILISING VERTEBRAE

The present invention relates to the domain of spinal osteosynthesis intended for surgery of the vertebral column, to correct malformations of the degenerative or idiopathic, neuromuscular or tumoral, or
5 of the traumatological type.

In prior art, it is known how to use an instrumentation comprising implants to be fixed on the bone, by screwing or by hooks and linkage elements enabling the surgeon to apply constraints for
10 straightening or stabilising the vertebral column.

As an example, the European patent EP626828 describes such a system enabling osteosynthesis on the vertebral column, together with a linkage element between this system and the tools used for assembly and/or
15 disassembly. This prior art document describes a device for osteosynthesis on the vertebral column, in particular for stabilising the vertebrae, comprising:

- at least one linkage element in the shape of a rod.

20 - at least two fixation elements each able to be anchored in a vertebra, these means having a head of the forked shape type whose two branches define a reception space closely U-shaped for the linkage element,

- a tightening screw able to be screwed in the
25 reception space to fix the linkage element between the two branches of the fork-shaped screw head,

- the head whose bottom of the reception space is shaped in the form of a concave cup corresponding with a tilting bushing element fitted between the bottom of the
30 reception space and the linkage element, the bushing

20019715.031502

element whose bearing surface opposite the reception space bottom is of a complementary convex shape, characterised in that the tilting bushing element is provided with a hemispherical bearing surface corresponding with the bottom of the reception space. This element is provided with a cut-out open from the tightening screw side in order to receive the linkage element in the form of a rod. The tilting bushing is maintained against the bottom of the reception space in such a way that it can tilt just as well in a plane parallel to the median plane of the reception space as in a perpendicular plane.

Patent PCT WO9101691 is also known, describing a device for straightening and propping up a vertebral column, constituted of screwed implants or hooks linked by at least two rods integrated together through the intermediary of connection and linkage elements. These rods are introduced longitudinally in grooves perpendicular to the screw, provided for this purpose in the body of the implants or hooks, then blocked in the bottom of the grooves. Integralisation of the rods is obtained with a threaded cross tie. A deformation by approaching the sides of the groove, set in the body of the implants or hooks, in order to obtain blocking of the rod in the bottom of the groove, is obtained through a system of cylindrical screw and conical threaded nut.

Patent WO9514437 is also known, revealing an implant comprising a part destined for anchoring the bone and a body for fixation on a rod, comprising two lateral branches defining a channel, this implant also comprising a threaded plug adapted in order to be screwed on the internal walls of the two branches. Another patent PCT

WO9410944 describes a device comprising a connection element set between a rod or other longitudinal implant, and a bone fixation screw placed in the degenerative vertebra. This connection element comprises a ring with dimensions such that the rod can pass through. The ring is provided with screws for fixing the rod and extends radially thanks to a cylindrical arm designed to be fixed to the fixation screw of the bone and tightened on the screw. The arm and the ring constitute a single part. This device allows the surgeon to avoid deforming the rod further when the latter is in the presence of non-aligned vertebral pedicles, leaving the surgeon total freedom to choose the placing of the two axes of the fixation screw of the bone and the rod.

The problem of devices of prior art is that of maintenance of the orientation decided by the surgeon at the time of the definitive fixation and of the dissociation between the positioning of the linkage element and the insertion of the bone implant. In the devices comprising a tightening screw, the tightening of this screw has a tendency to modify the relative orientation of the linkage rods and the fixation element.

Another problem is that of adjusting the setting of the screws during the realignment stage of the vertebral column by rotation of the correction rod. This correction rod crosses through numerous vertebral implants, for example 10 to 15 implants and/or vertebral screws. Generally, each of these implants comprises a blocking screw. This blocking screw must be sufficiently tightened to avoid slipping from the vertebral implant, but not too tight in order to allow rotation of the rod without excessive friction. The adjustment of the degree of

screwing of each of these blocking screws is a fastidious and delicate operation.

The aim of the invention is to avoid these inconveniences by proposing a system and an implant making it possible to preserve the degree of correction decided by the surgeon during the operations of definitive fixation and tightening of blocking screws of the linkage element. The aim is also to allow rotation of the rod during its rotational manoeuvring, with minimum friction independent of the degree of tightening of the blocking screw.

Thus, the aim of the invention concerns in its most general form a device for osteosynthesis on the vertebral column, in particular for the stabilisation of vertebrae, comprising:

- at least one linkage element in the form of a rod, or plate,

- at least two means of fixation each able to be anchored into a vertebra, these means having a head in the shape of a fork whose two branches define a reception space closely in the form of a "U" for the linkage element,

- a blocking screw capable of being screwed in the reception space to fix the linkage element positioned between the two branches of the forked shape screw head, characterised in that the bottom of the head has the general shape of a horse saddle, in that the head has a guide means for an independent closure part capable of being fixed on the head after positioning the linkage element in the fork of the head, said closure part being in the general form of a "U" with branches coming into co-operation with the branches of the part in the shape

of a "Y" fork for the head, and whose bottom comprises a threading for co-operation with the blocking screw and in that the guide means provided on the head are formed by an arched shoulder on the external lateral surfaces of the fork shaped part.

The horse-saddle shape can be described as an inverse hyperbolic paraboloid, according to a particular embodiment but it is not limited to a shape engendered by a second degree equation corresponding to a hyperbolic paraboloid.

This embodiment makes it possible first of all to insert the fixation means on the vertebral column, then the linkage elements possibly at the same time as the closure part, then to adjust the correction independently from the locking element, and when the optimum correction has been obtained, to block each implant by the blocking screws. The tightening of the blocking screws does not modify the orientation of the fixation means because of the degree of freedom of movement of the closure part relative to the body of the fixation means.

The closure part has two lateral branches which are flexibly malleable, with an arched shoulder on the interior surfaces. The dimensions and shapes of branches and shoulders are determined in such a way as to allow the setting of the closure part by flexible spacing of the branches and the interlocking of the shoulders. The final locking of the closure part and the implant is produced by tightening the blocking screw. The guide means of the closure part on the head is formed by a complementary arched shoulder provided on the external lateral surfaces of the fork-shaped part. This arched

shoulder allows rotation of the closure part relative to the head of the implant.

A variant consists of producing a closure part having a shape memory. Such a part has spread arms at rest, to allow setting on the fork-shaped part. When it is in position on the head of the hook, a modification of temperature makes the arms fold back into an anchoring position on the fork.

According to a preferred embodiment, the shoulders have contact surfaces converging closely towards the threading intended to receive the blocking screw.

According to a variant, the position of the closure part is fixed relative to the head fork. The shoulder or the interlocking means, according to this variant, do not allow a degree of rotational freedom of the closure part.

The angle of convergence is not very critical. It is only important that the contact surfaces should be oriented towards the bottom of the closure part. However, an angle of about ten degrees relative to the transversal plane would already make it possible to obtain a satisfactory guiding.

According to an embodiment variant, the head is prolonged by a lower part in the shape of a hook for maintaining the vertebral column for the setting on a pedicle, vertebra lamina or transverse process, said hook comprising a flexible lamina for temporary maintenance of the fixation.

The invention surely relates to the system comprising the components as a whole (correction rod, implants, closure parts, blocking screws). Nonetheless it also relates to the fixation element capable of being anchored onto a vertebra, for the osteosynthesis

instrumentation. This fixation element can be used with linkage elements other than rods, for example a linkage element with a trapezoid or variable cross-section, or laminae, in particular laminae having linkage zones of circular cross-section.

The invention also concerns an ancillary for the implementation of a system for osteosynthesis according to the invention characterised in that it presents two jaws which come to lodge in the cut-outs provided on the head of the implant, and a device exerting a force on the rod to ensure its lateral and/or vertical displacement, with the intention of enabling the positioning of the rod in the fork. This effort can be exerted on the rod through the intermediary of the closure part with which the ancillary co-operates during the phase of setting the rod in place in the fork of the implant. The co-operation can be carried out by temporary screwing of the ancillary in the threading of the closure part.

The invention will be better understood by reading the following description of the attached drawings wherein:

- figure 1 shows a longitudinal cross-section of an embodiment of an osteosynthesis system according to the invention;

- figure 2 shows a diagram from the side of the system according to the invention, and

- figures 3 and 4 show a view of the implant according to two perpendicular faces.

The osteosynthesis system according to the present invention comprises a linkage element (1), an implant (2) with a complementary closure part (3), and a blocking screw (13).

The rod (1) will not be described in greater detail since it belongs to the present state of the art and can take diverse forms. In the example given, it is formed of a metallic rod with a circular cross-section.

5 The implant has a fork shaped head (5), with two lateral arms (6, 7) defining a space intended to receive the linkage element (1).

10 The bottom (8) of the fork is generally horse-shoe shaped, with a concave curve in the transversal plane corresponding to the plane of figure 1, and a convex curve in the complementary plane.

15 The radius of the concave curve corresponds closely to the external radius of the guiding element (1). The latter thus comes into contact following a semi-peripheral line. This contact according to a line and not according to an annular surface allows a degree of pivoting freedom, and at the same time ensures more efficient blocking after tightening than in the case of a simple pinpoint contact.

20 The closure part (3) has a general "U" shape, with two arms (10, 11) and a bottom with a threading (12) to receive a blocking screw.

25 The arms (10, 11) have a spacing allowing the head to be put into place. At their lower extremity the arms (10, 11) have arched shoulders (14, 15) with an upper inclined surface (16, 17).

30 These arched shoulders (14, 15) co-operate with the complementary guide means (20, 21) provided on the head (5). These guide means also have an inclined arched contact surface (22, 23), and co-operate with the complementary contact surfaces (14, 15) when the closure part is set in place on the head (5). They then ensure a

guiding allowing pivoting of the closure part along a transversal axis (24) and ensure the locking of the closure part (3) on the head (5), and thus the blocking of the rod (1) after tightening the screw (13).

Figure 2 is a side view showing that the rod (1) has a degree of freedom tilting around a transversal axis (24). This makes it possible to give the implant independence, and to position the implant by means of the hook (26) on the pedicle, and independently to search for the best orientation of the rod (1) without interference between these two restrictions. The horse-shoe shape and the mobility of the closure part make it possible to adapt the locking and to avoid de-rotation or displacement of the rod during tightening of the screw (13).

The hook (26) defines a "U-shaped" space (27) for linkage with the lamina of a vertebra. In order to ensure temporary maintenance, a flexible lamina (28) is set inside this "U" space and ensures a temporary maintenance on the bone in such a way that there is no risk of the lamina of the hook disturbing the spinal cord or any other structure.

The flexible lamina (28) pushes back the hook in a posterior direction relative to the patient, and avoids lesions of the noble tissues during the phase of correction by rotation of the rod.

Figures 3 and 4 show side views of the implant, without the closure part.

The implant has two cut-outs (30, 31) allowing the passage of an instrument with two jaws to lodge in the cut-outs (30, 31), and a device exerting an effort on the rod to ensure its lateral and/or vertical displacement,

in order to allow the positioning of the rod in the fork through the intermediary of the closure part (3). In this case, one part of the instrument is integrated temporarily with the closure part with the aid of a screw introduced in the threading (12) of the closure part (3).

The invention is described above as a non-limiting example. It is understood that those skilled in the art can produce diverse variants, in particular by replacing the hook by a pedicle screw, or a vertebral screw for inserting on the anterolateral face of the vertebral column.

1004434001

CLAIMS

1. System for osteosynthesis on the vertebral column, in particular for stabilisation of vertebrae, comprising:

- at least one linkage element (1) in the form of a rod,

5 - at least two means of fixation each able to be anchored into a vertebra, these means having a head (5) in the shape of a fork whose two branches define a reception space closely in the form of a "U" for the linkage element,

10 - a blocking screw (13) capable of being screwed in the reception space to fix the linkage element (1) between the two branches of the fork shaped screw head (5),

characterised in that the bottom of the head (5) has
15 the general shape of a horse saddle, in that the head (5) has a guide means for an independent closure part, capable of being fixed on the head (5) after positioning the linkage element (1) in the fork of the head (5), said closure part (3) being in the general shape of a "U" with
20 branches co-operating with the branches of the fork shaped part of the head (5), and whose bottom comprises a threading for co-operation with the blocking screw (13) and in that the guide means provided on the head (5) are formed by an arched shoulder on the external lateral
25 surfaces of the fork shaped part..

2. System for osteosynthesis on the vertebral column, in particular for stabilisation of vertebrae according to claim 1, characterised in that the closure part has a
30 complementary shoulder for guide means, the shoulder

dimensions and shapes being determined in such a way as to allow the setting of the closure part (3) by flexible spacing or shape memory of the branches and anchoring by contacting the transversal surfaces of the shoulders during tightening of the screw (13).

3. System for osteosynthesis on the vertebral column, in particular for stabilisation of vertebrae according to claim 2, characterised in that the shoulders provided on the lateral surfaces of the fork shaped head part (5) are in the shape of an arc of a circle.

4. System for osteosynthesis on the vertebral column, in particular for stabilisation of vertebrae according to one or the other of claims 2 or 3, characterised in that the shoulders have contact surfaces converging closely towards the threading intended to receive the blocking screw (13).

5. System for osteosynthesis on the vertebral column, in particular for stabilisation of vertebrae according to at least one of the preceding claims, characterised in that the head (5) is prolonged by a lower part in the shape of a hook for setting in place on a pedicle or other, said hook comprising a flexible lamina for temporary maintenance.

6. Fixing element capable of being anchored onto a vertebra, for osteosynthesis instrumentation, of the type with a head (5) in the shape of a fork whose two branches define a reception space closely in the form of a "U" for the linkage element, characterised in that the bottom of

the head (5) has the general shape of a horse saddle, and in that the head (5) has a guide means for an independent closure part (3), capable of being fixed on the head (5) after positioning the linkage element (1) in the fork of the head (5), said closure part (3) being in the general form of a "U" with branches co-operating with the branches of the part in the fork shaped head (5), and whose bottom comprises a threading for co-operation with the blocking screw (13) and in that the guide means provided on the head (5) are formed by an arched shoulder on the external lateral surfaces of the fork shaped part.

7. Fixing element capable of being anchored onto a vertebra, for osteosynthesis instrumentation, according to claim 6, characterised in that the closure part (3) has a complementary shoulder, the dimensions and shapes of shoulders being determined in such a way as to allow the setting of the closure part (3) by flexible spacing or shape memory of the branches and anchoring by contacting the transversal surfaces of the shoulders during the tightening of the screw.

8. Fixing element capable of being anchored onto a vertebra, for osteosynthesis instrumentation according to claim 7, characterised in that the shoulders provided on the lateral surfaces of the fork shaped part of the head (5) are in the form of an arc of a circle, allowing a unique degree of freedom of the rod relative to the fixation implant on the vertebral column.

9. System for osteosynthesis on the vertebral column, in particular for stabilisation of the vertebrae according

to one or the other of claims 6 or 7, characterised in that the shoulders have contact surfaces converging closely on the threading intended to receive the blocking screw (13).

5

10. System for osteosynthesis on the vertebral column, in particular for stabilisation of the vertebrae according to at least one of claims 6 to 9, characterised in that it is prolonged by a lower part in the form of a hook for setting in place on the vertebra, said hook comprising a flexible lamina (28) for temporary maintenance of the fixation.

11. Ancillary for the implementation of a system for osteosynthesis according to one or the other of claims 9 or 10, characterised in that it has two jaws which lodge in the cut-outs (30, 31) provided on the head (5) of the implant, and a device exerting a force on the rod to ensure its lateral and/or vertical displacement, with the aim of enabling the positioning of the rod in the fork.

12. Ancillary for the implementation of a system for osteosynthesis according to one or the other of claims 9 or 10, characterised in that it has a linkage zone with the closure part (3) through the intermediary of a temporary screw co-operating with the threading (12).

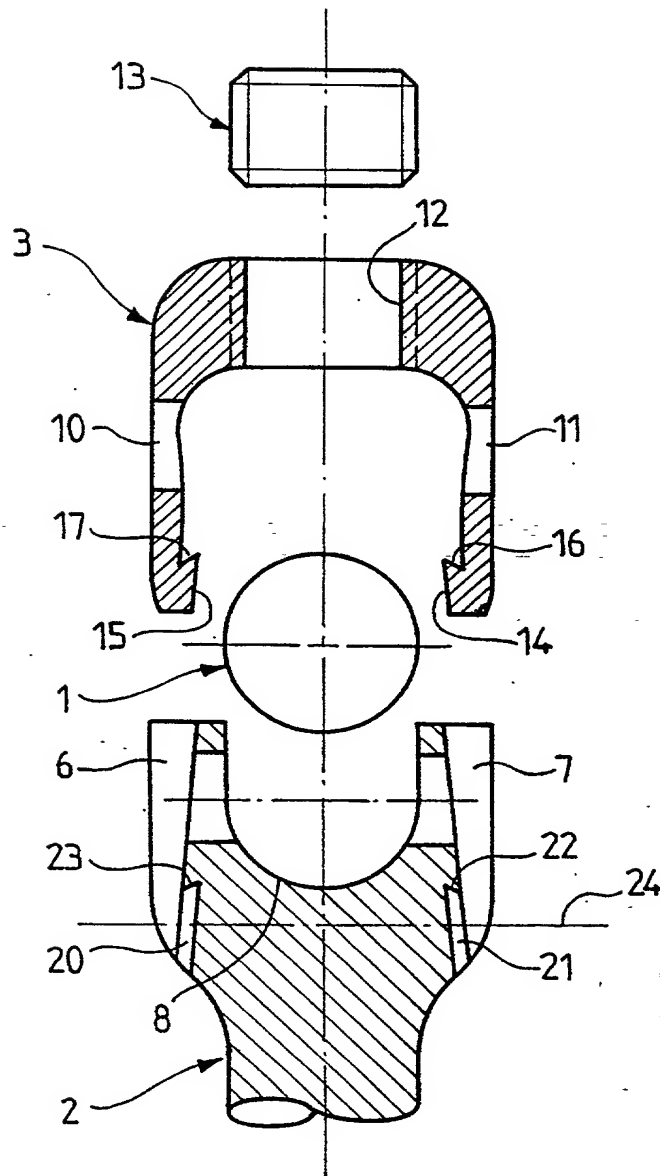


FIG.1

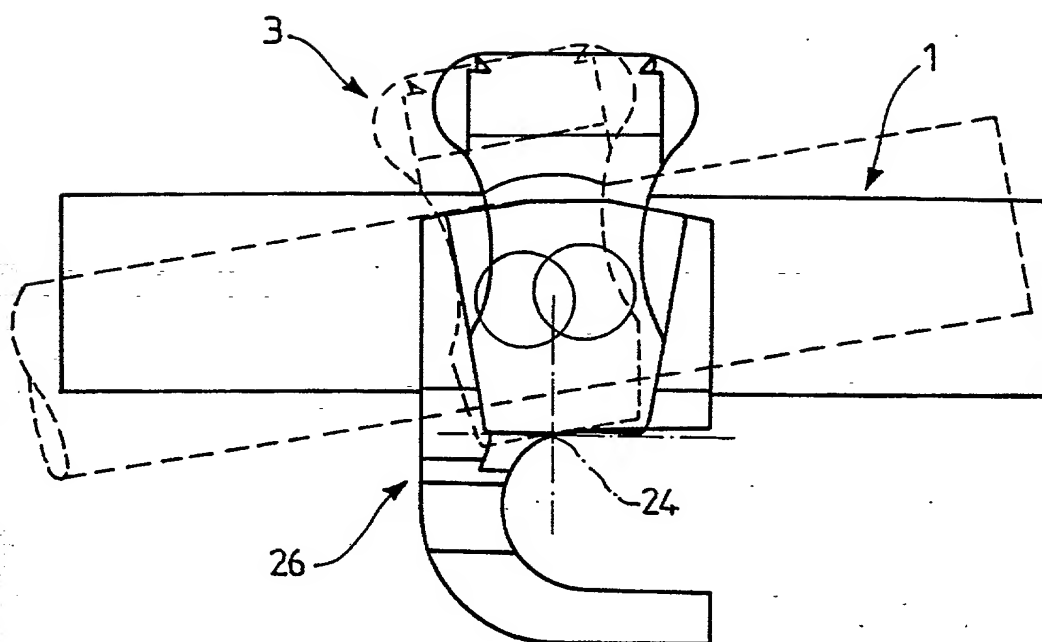


FIG. 2

3/3

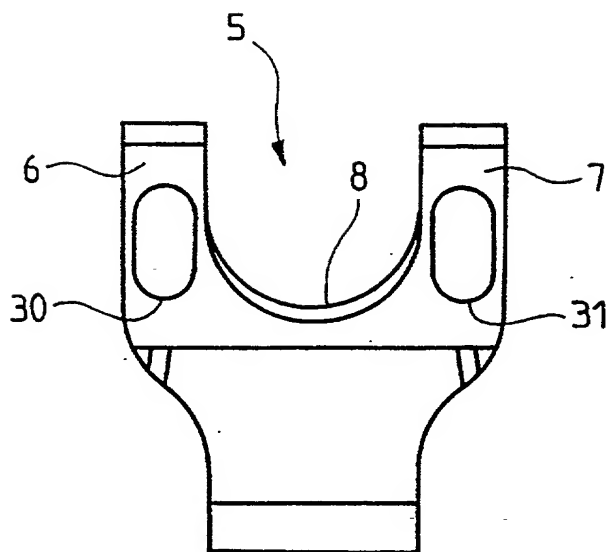


FIG. 3

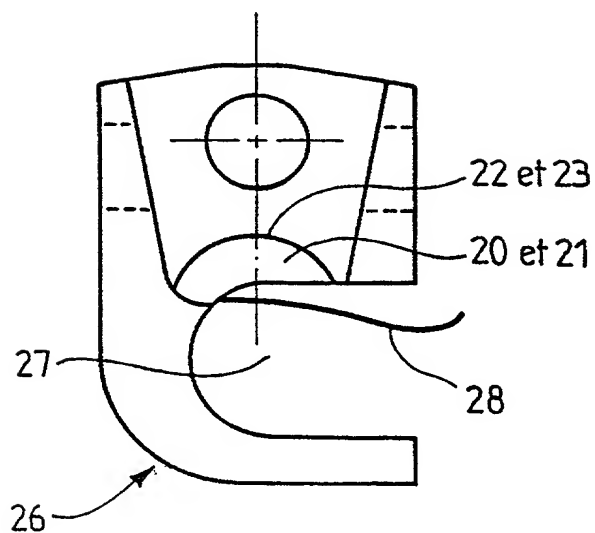


FIG. 4

**ALL FOREIGN APPLICATION(S), IF ANY, FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION**

NOTE: If the application filed more than 12 months from the filing date of this application is a PCT filing forming the basis for this application entering the United States as (1) the national stage, or (2) a continuation, divisional, or continuation-in-part, then also complete ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR C-I-P APPLICATION for benefit of the prior U.S. or PCT application(s) under 35 U.S.C. § 120.

POWER OF ATTORNEY

I hereby appoint the following practitioner(s) to prosecute this application and transact all business in the Patent and Trademark Office connected therewith.

(list name and registration number)

Robert H. Bachman (19,374), Gregory P. LaPointe (28,395),
Barry L. Kelmachter (29,999), George A. Coury (34,309), and
Jeffrey R. Ambroziak (47,387), all of Bachman & LaPointe, P.C.,
900 Chapel Street, Suite 1201, New Haven, CT 06510-2802
(check the following item, if applicable)

- ☒ I hereby appoint the practitioner(s) associated with the Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith.
- ☐ Attached, as part of this declaration and power of attorney, is the authorization of the above-named practitioner(s) to accept and follow instructions from my representative(s).

SEND CORRESPONDENCE TO

- ☒ Address
Bachman & LaPointe, P.C.
900 Chapel Street, Suite 1201
New Haven, CT 06510-2802

DIRECT TELEPHONE CALLS TO:
(Name and telephone number)

Barry L. Kelmachter
(203) 777-6628 - ext. 114

- ☐ Customer Number _____

10019715-031502

SUPPLEMENTAL DECLARATION (37 C.F.R. § 1.67(b))*(complete the following where a supplemental declaration is being submitted)*

- ☐ I hereby declare that the subject matter of the
- ☐ attached amendment
- ☐ amendment filed on _____

was part of my/our invention and was invented before the filing date of the original application, above-identified, for such invention.

ACKNOWLEDGEMENT OF REVIEW OF PAPERS AND DUTY OF CANDOR

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information, which is material to patentability as defined in 37, Code of Federal Regulations, § 1.56,

(also check the following items, if desired)

- ☒ and which is material to the examination of this application, namely, information where there is a substantial likelihood that a reasonable Examiner would consider it important in deciding whether to allow the application to issue as a patent, and
- ☐ in compliance with this duty, there is attached an information disclosure statement, in accordance with 37 C.F.R. § 1.98.

PRIORITY CLAIM (35 U.S.C. §§ 119(a)-(d))

NOTE: "The claim to priority need be in no special form and may be made by the attorney or agent if the foreign application is referred to in the oath or declaration as required by § 1.63. The claim for priority and the certified copy of the foreign application specified in 35 U.S.C. 119(b) must be filed in the case of an interference (§ 1.630), when necessary to overcome the date of a reference relied upon by the examiner, when specifically required by the examiner, and in all other situations, before the patent is granted. If the claim for priority or the certified copy of the foreign application is filed after the date the issue fee is paid, it must be accompanied by a petition requesting entry and by the fee set forth in § 1.17(i). If the certified copy is not in the English language, a translation need not be filed except in the case of interference; or when necessary to overcome the date of a reference relied upon by the examiner; or when specifically required by the examiner, in which event an English language translation must be filed together with a statement that the translation of the certified copy is accurate." 37 C.F.R. § 1.55(a).

I hereby claim foreign priority benefits under Title 35, United States Code, §§ 119(a)-(d) of any foreign application(s) for patent or inventor's certificate or of any PCT international application(s) designating at least one country other than the United States of America listed below and have also identified below any foreign application(s) for patent or inventor's certificate or any PCT international application(s) designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the application(s) of which priority is claimed.

(complete (d) or (e))

- (d) ☐ no such applications have been filed.
- (e) ☒ such applications have been filed as follows.

NOTE: Where item (c) is entered above and the International Application which designated the U.S. itself claimed priority check item (e), enter the details below and make the priority claim.

(Declaration and Power of Attorney [1-1]—page 3 of 7)

10019715.031502

**PRIOR FOREIGN/PCT APPLICATION(S) FILED WITHIN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS APPLICATION
AND ANY PRIORITY CLAIMS UNDER 35 U.S.C. § 119(a)-(d)**

| COUNTRY (OR INDICATE IF PCT) | APPLICATION NUMBER | DATE OF FILING (day, month, year) | PRIORITY CLAIMED UNDER 37 USC 119 |
|------------------------------------|--------------------|--------------------------------------|--|
| FRANCE | 99/08498 | 01/07/1999 | <input checked="" type="checkbox"/> YES NO <input type="checkbox"/> |
| | | | <input type="checkbox"/> YES NO <input type="checkbox"/> |
| | | | <input type="checkbox"/> YES NO <input type="checkbox"/> |
| | | | <input type="checkbox"/> YES NO <input type="checkbox"/> |
| | | | <input type="checkbox"/> YES NO <input type="checkbox"/> |

**CLAIM FOR BENEFIT OF PRIOR U.S. PROVISIONAL APPLICATION(S)
(34 U.S.C. § 119(e))**

I hereby claim the benefit under Title 35, United States Code, § 119(e) of any United States provisional application(s) listed below:

PROVISIONAL APPLICATION NUMBER

FILING DATE

____ / _____
 ____ / _____
 ____ / _____

**CLAIM FOR BENEFIT OF EARLIER US/PCT APPLICATION(S)
UNDER 35 U.S.C. § 120**

- ☐ The claim for the benefit of any such applications are set forth in the attached ADDED PAGES TO COMBINED DECLARATION AND POWER OF ATTORNEY FOR DIVISIONAL, CONTINUATION OR CONTINUATION-IN-PART (C-I-P) APPLICATION.

(Declaration and Power of Attorney [1-1]—page 4 of 7)

10019715.031502

Practitioner's Docket No. 01-765**PATENT****COMBINED DECLARATION AND POWER OF ATTORNEY**(ORIGINAL, DESIGN, NATIONAL STAGE OF PCT, SUPPLEMENTAL, DIVISIONAL,
CONTINUATION, OR C-I-P)

As a below named inventor, I hereby declare that:

TYPE OF DECLARATION

This declaration is of the following type:

(check one applicable item below)

- ☐ original.
☐ design.
☐ supplemental.

NOTE: If the declaration is for an International Application being filed as a divisional, continuation or continuation-in-part application, do not check next item; check appropriate one of last three items.

- ☒ national stage of PCT.

NOTE: If one of the following 3 items apply, then complete and also attach ADDED PAGES FOR DIVISIONAL, CONTINUATION OR C-I-P.

NOTE: See 37 C.F.R. § 1.63(d) (continued prosecution application) for use of a prior nonprovisional application declaration in the continuation or divisional application being filed on behalf of the same or fewer of the inventors named in the prior application.

- ☐ divisional.
☐ continuation.

NOTE: Where an application discloses and claims subject matter not disclosed in the prior application, or a continuation or divisional application names an inventor not named in the prior application, a continuation-in-part application must be filed under 37 C.F.R. § 1.53(b) (application filing requirements — nonprovisional application).

- ☐ continuation-in-part (C-I-P).

INVENTORSHIP IDENTIFICATION

WARNING: If the inventors are each not the inventors of all the claims, an explanation of the facts, including the ownership of all the claims at the time the last claimed invention was made, should be submitted.

My residence, post office address and citizenship are as stated below, next to my name. I believe that I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed, and for which a patent is sought on the invention entitled:

TITLE OF INVENTIONFIXING ELEMENT AND ANCILLARY FOR STABILISING VERTEBRAE

10019715.031502

SPECIFICATION IDENTIFICATION

the specification of which:

(complete (a), (b), or (c))

(a) ☐ is attached hereto.

NOTE: "The following combinations of information supplied in an oath or declaration filed on the application filing date with a specification are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 CFR 1.63:

"(1) name of inventor(s), and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration on filing;

"(2) name of inventor(s), and attorney docket number which was on the specification as filed; or

"(3) name of inventor(s), and title which was on the specification as filed."

Notice of July 13, 1995 (1177 O.G. 60).

(b) ☒ was filed on December 28, 2001, as ☒ Serial No. X0XX 10/019,715
or ☐ _____
and was amended on _____ (if applicable).

NOTE: Amendments filed after the original papers are deposited with the PTO that contain new matter are not accorded a filing date by being referred to in the declaration. Accordingly, the amendments involved are those filed with the application papers or, in the case of a supplemental declaration, are those amendments claiming matter not encompassed in the original statement of invention or claims. See 37 C.F.R. § 1.67.

NOTE: "The following combinations of information supplied in an oath or declaration filed after the filing date are acceptable as minimums for identifying a specification and compliance with any one of the items below will be accepted as complying with the identification requirement of 37 CFR 1.63:

"(A) application number (consisting of the series code and the serial number, e.g., 08/123,456);

"(B) serial number and filing date;

"(C) attorney docket number which was on the specification as filed;

"(D) title which was on the specification as filed and reference to an attached specification which is both attached to the oath or declaration at the time of execution and submitted with the oath or declaration; or

"(E) title which was on the specification as filed and accompanied by a cover letter accurately identifying the application for which it was intended by either the application number (consisting of the series code and the serial number, e.g., 08/123,456), or serial number and filing date. Absent any statement(s) to the contrary, it will be presumed that the application filed in the PTO is the application which the inventor(s) executed by signing the oath or declaration."

M.P.E.P. § 601.01(a), 7th Ed.

(c) ☒ was described and claimed in PCT International Application No. PCT/FR00/01872, filed on June 30, 2000 and as amended under PCT Article 19 on _____ (if any).

(Declaration and Power of Attorney [1-1]—page 2 of 7)

DECLARATION

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

SIGNATURE(S)

NOTE: Carefully indicate the family (or last) name, as it should appear on the filing receipt and all other documents.

NOTE: Each inventor must be identified by full name, including the family name, and at least one given name without abbreviation together with any other given name or initial, and by his/her residence, post office address and country of citizenship. 37 CFR § 1.63(a)(3).

NOTE: Inventors may execute separate declarations/oaths provided each declaration/oath sets forth all the inventors. Section 1.63(a)(3) requires that a declaration/oath, inter alia, identify each inventor and prohibits the execution of separate declarations/oaths which each sets forth only the name of the executing inventor. 62 Fed. Reg. 53,131, 53,142, October 10, 1997.

Full name of sole or first inventor

10010715.031502
1-00
Gerard M Vanacker
(GIVEN NAME) (MIDDLE INITIAL OR NAME) FAMILY (OR LAST NAME)
Inventor's signature [Signature]
Date Feb 4, 2002 Country of Citizenship France
Residence 52, avenue Francois Adam, 94100 Saint Maur, FRANCE JRL
Post Office Address (Same As Above)

Full name of second joint inventor, if any

2-0
Reinhard DiK Zeller
(GIVEN NAME) (MIDDLE INITIAL OR NAME) FAMILY (OR LAST NAME)
Inventor's signature [Signature]
Date 02/05/02 Country of Citizenship France
Residence 127 rue Jean-Baptiste Clement, F-92100 Boulogne, FRANCE JRL
Post Office Address (Same As Above)

Full name of third joint inventor, if any

~~Reinhard DiK ZELLER~~
~~(GIVEN NAME) (MIDDLE INITIAL OR NAME) FAMILY (OR LAST NAME)~~
~~Inventor's signature~~
~~Date 02/05/02 Country of Citizenship FRANCE~~
~~Residence 127~~
~~Post Office Address~~

(Declaration and Power of Attorney [1-1]—page 6 of 7)

(check proper box(es) for any of the following added page(s)
that form a part of this declaration)

- ☐ **Signature** for fourth and subsequent joint inventors. *Number of pages added* _____

* * *

- ☐ **Signature** by administrator(trix), executor(trix) or legal representative for deceased or incapacitated inventor. *Number of pages added* _____

* * *

- ☐ **Signature** for inventor who refuses to sign or cannot be reached by person authorized under 37 CFR 1.47. *Number of pages added* _____

* * *

- ☐ Added page for **signature** by one joint inventor on behalf of deceased inventor(s) where legal representative cannot be appointed in time. (37 CFR 1.47)

* * *

- ☐ Added pages to combined declaration and power of attorney for divisional, continuation, or continuation-in-part (C-I-P) application.

☐ *Number of pages added* _____

* * *

- ☐ Authorization of practitioner(s) to accept and follow instructions from representative.

* * *

(if no further pages form a part of this Declaration,
then end this Declaration with this page and check the following item)

- ☒ This declaration ends with this page.

10019715, 031502